DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
300 Pearl Street, Suite 100
Buffalo, NY 14202

December 4, 2006

WARNING LETTER NYK 2007-04

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mathew A. Lamb, Partner
Jonathan L. Lamb, Partner
Lamb Farms, Inc.
6880 Albion Road
Oakfield, New York 14125

Dear Messrs. Lamb:

An inspection of your dairy farm operation located at 6880 Albion Road and 3962 Oakfield-Elba Townline Rd., Oakfield, New York was conducted by representatives of the U.S. Food and Drug Administration (FDA) on August 8 and 9, 2006. This inspection confirmed that you offered two animals for sale for slaughter as food that were adulterated under section 402(a)(2)(C)(ii) [21 U.S.C. § 342(a)(2)(C)(ii)] of the Federal Food, Drug, and Cosmetic Act (the Act). The inspection also revealed that you caused the new animal drug Pen-G Max™ Procaine Penicillin G in Aqueous Suspension, NADA 65-110, to be unsafe under section 512 [21 U.S.C. § 360b] of the Act and adulterated within the meaning of section 501(a)(5) [21 U.S.C. § 351(a)(5)] of the Act . You can find the Act and its associated regulations on the Internet through links on the FDA's web page at www.fda.gov.

On or about February 9, 2006, you consigned a dairy cow identified with metal ear tag 21ZLX1525 and farm tag 12525 for slaughter as food to cattle dealer [redacted] further identified the cow with back tag [redacted]. The cow was subsequently delivered to [redacted], and slaughtered there on or about February 10, 2006. United States Department of Agriculture, Food Safety and Inspection Service (USDA/FSIS) analyses revealed 0.21 parts per million (ppm) penicillin in kidney tissue. A tolerance of 0.05 ppm has been established for residues of penicillin in uncooked edible tissues of cattle Title 21, Code of Federal Regulations (C.F.R.), Part 556.510 (21 C.F.R. 556.510). The presence of this drug in this amount in the edible tissues of this animal causes the food to be adulterated within the meaning of section 402(a)(2)(C)(ii) [21 U.S.C. § 342(a)(2)(C)(ii)] of the Act.

On or about April 3, 2006, you consigned a dairy cow identified with farm tag 1127 for slaughter as food to cattle dealer [redacted]. [redacted] further identified the cow with back tag [redacted]. The cow was subsequently delivered to [redacted], and slaughtered there on or about April 4, 2006. USDA/FSIS analyses revealed 2.86 ppm sulfadimethoxine in liver tissue and 1.21 ppm sulfadimethoxine in the muscle tissue. A tolerance of 0.1 ppm has been established for residues of sulfadimethoxine in the uncooked edible tissues of cattle (21 C.F.R. 556.640). The presence of this drug in this amount in edible tissues from this animal causes the food to be adulterated within the meaning of section 402(a)(2)(C)(ii) [21 U.S.C. § 342(a)(2)(C)(ii)] of the Act.

In addition, you adulterated Pen-G Max™ Procaine Penicillin G in Aqueous Suspension, NADA 65-110, within the meaning of section 501(a)(5) [21 U.S.C. § 351(a)(5)] of the Act when you failed to use the drug in conformance with its approved labeling and the labeling added by your veterinarian. "Extralabel use," i.e., the actual or intended use of a drug in an animal in a manner that is not in accordance with the approved labeling, is only permitted if the use is by or on the lawful order of a licensed veterinarian within the context of a valid veterinarian/client/patient relationship. The extralabel use of approved veterinary or human drugs must comply with sections 512(a)(4) [21 U.S.C. § 360b(a)(4)] and 512(a)(5) [21 U.S.C. § 360b(a)(5)] of the Act and 21 C.F.R. Part 530. Our investigation found that your extralabel use of Pen-G Max™ Procaine Penicillin G in Aqueous Suspension, NADA 65-110, failed to comply with these requirements.

For example, you administered Pen-G Max™ Procaine Penicillin G in Aqueous Suspension, NADA 65-110, without following the approved labeling instructions and the added labeling of your veterinarian in that you administered it at a rate of 60 ml intramuscularly once daily for three days. The approved labeling instructions for this drug state it is for intramuscular use at a daily rate of 1 ml/100 lbs. of body weight for no more than four consecutive days and not to exceed 10 ml per injection site. Your veterinarian's added labeling instructions directed you to use the drug for the treatment of [redacted]. You administered this drug contrary to both the approved labeling instructions and those of your veterinarian. You did so without the supervision of a licensed veterinarian (i.e., you did not consult with your veterinarian before deviating from his instructions), in violation of 21 C.F.R. 530.11(a).

Furthermore, your extralabel use resulted in an illegal drug residue, in violation of 21 C.F.R. 530.11(d). Because your extralabel use of this drug was not in compliance with 21 C.F.R. Part 530, your use caused the drug to be unsafe under section 512(a) [21 U.S.C. § 360b(a)] of the Act and adulterated within the meaning of section 501(a)(5) [21 U.S.C. § 351(a)(5)] of the Act.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for ensuring that your overall operation and the food you distribute is in compliance with the law.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and/or injunction.

You should notify this office in writing of the steps you have taken to bring your firm into compliance with the law within fifteen (15) working days of receiving this letter. Your response should include each step that has been taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your written response should be sent to Patricia A. Clark, Compliance Officer, U.S. Food and Drug Administration, 300 Pearl Street, Suite 100, Buffalo, New York 14202. If you have any questions about this letter, please contact Compliance Officer Patricia A. Clark at 716-551-4461, extension 3168.

Sincerely yours,

Otto D. Vitillo
District Director
New York District